"COMPARISON OF BEHAVIORAL AND PHYSIOLOGICAL RESPONSES TO INTRANASAL AND SUBLINGUAL MIDAZOLAM SEDATION – A RANDOMIZED CONTROLLED TRIAL"

Aim

The aim of the study was to assess the changes in the anxiety level and behavior of the children after intranasal and sublingual midazolam sedation.

Objectives

1. To assess the behavior of the child using Modified Houpt Behavior rating scale after intranasal and sublingual midazolam sedation
2. To assess the child's anxiety before, after and during the procedure using Venham's clinical anxiety scale.
3. To assess the change in physiological parameters such as blood pressure, heart rate, oxygen saturation.
4. To assess the acceptance of the drug by the child using a four point acceptance scale.
5. To assess the Onset of action of the drug by observing the signs such as drowsiness, drooping of eyelids, slurred speech and calming of the child.

Methodology

The present study was conducted in the Department of Pedodontics and Preventive Dentistry, KSR Institute of Dental Science and Research. After the approval from Institutional review board, a randomized controlled trial was planned. Forty children aged 3 to 7 years participated in the study. After obtaining written consent from their parents/guardians and anesthetic fitness approval, twenty children in each group received 0.2mg/kg midazolam either

by intranasal or sublingual route. Twenty minutes after the drug administration various treatment procedures which require local anesthetic administration such as restoration, pulp therapy and extractions were done. The whole procedure was videotaped. The child's behavior and anxiety were assessed using Modified Houpt and Venham's anxiety scale by two independent pediatric dentist with interobserver reliability kappa=0.755. The Modified Houpt behavior rating scale consists of three major categories such as sleep, cry and movement. The assessments were made at the following time intervals: B (baseline when no procedure was done before the drug administration), S(20 minutes after the drug administration), LA(during local anesthetic administration, ever 5 minutes during the operative procedure (T_1, T_2, T_3 and T_4). The physiological parameters such as heart rate, blood pressure and oxygen saturation were monitored and recoded throughout the procedure.

Statistical Analysis

Mann Whitney U test and Wicoxon signed rank test were used appropriately

Results

1. Children who received midazolam by intranasal route (9.40±1.847) showed a significant faster onset of action than the sublingual route (13.80±2.042).
2. Sublingual route of midazolam administration showed a better acceptance to the drug than intranasal route.
3. In intranasal group a significant decrease in anxiety at various time periods (After 20 minutes, LA, T_1, T_2, T_3, and T4) were seen when compared to the baseline.
4. In the sublingual group there was a significant decrease in the anxiety level 20 minutes after the drug administration and during the initial 10 minutes of the operative procedure (T_1, T_2) when compared to the baseline.

5. There was a significant increase in the anxiety during local anesthetic administration in both intranasal ($p=0.001$) and sublingual ($p<0.001$) group.
6. There was no significant difference between the changes in anxiety levels between both the groups at various time periods.
7. There was no significant difference in the modified houpt behavior rating scale (sleep, cry, movement and the overall behavior) of the children between group A and B at various time periods.
8. In the sublingual group there was a significant increase in the heart during 10 minutes after the start till the end of the operative procedure.
9. There were no significant changes in the blood pressure, oxygen saturation in both the intranasal and sublingual group throughout the operative procedure.
10. No adverse effects such as apnoea, airway obstruction, laryngospasm, vomiting, hypotension and cardiopulmonary impairment has been observed in the study.

Conclusion

Intranasal and sublingual midazolam sedation along with simple behavior management techniques can be used safely by pediatric dentists to effectively manage and instill a positive behavior in young and anxious children.

Key Words: Intranasal, Moderate sedation, Midazolam, Sublingual, Houpt behavior, Venham's clinical anxiety, Onset, Acceptance.